IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FMC CORPORATION,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	
SHARDA USA LLC,	:	**NO. 24-2419**
Defendant.	:	

PEREZ, J. **August 16, 2024**

MEMORANDUM

On July 10, 2024, the Court denied Plaintiff FMC Corporation's ("FMC") Motion for a Temporary Restraining Order and Preliminary Injunction without prejudice. Now before the Court is FMC's Renewed Motion for a Temporary Restraining Order and Motion for Expedited Discovery. For the reasons set forth more fully below, the Court will grant FMC's Motion for a Temporary Restraining Order.

I. BACKGROUND[1]

In 2007, FMC registered with the EPA the first zeta-cypermethrin 3.75% w/w + bifenthrin 11.25% w/w pesticide product named HERO®. ECF 30-4 ¶ 27. On July 2, 2022, Sharda filed an application to register a pesticide product with EPA. *Id.* ¶ 28. The product's proposed registration name was "Sharda Bifen. 11.25% + Zeta-Cyper. 3.75% EC." *Id.* To support its application, Sharda submitted several studies to the EPA, including one regarding the "Accelerated Storage Stability of Zeta-Cypermethrin 3.75% w/w + Bifenthrin 11.25% w/w EC." *Id*. Sharda also submitted data to meet the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") product chemistry

[1] The underlying facts are more fully set forth in the Court's July 10, 2024, memorandum opinion.

requirements. *Id.* ¶ 29. Sharda did not submit acute toxicology data, which is not required when the proposed product is identical or substantially similar to another registered product. *Id.* ¶ 30.

From July 22, 2022 through February 1, 2023, Sharda sent FMC three separate "offer-to-pay" letters. *Id.* ¶ 32. In the letters, Sharda noted that FMC "is listed on the most recent EPA 'Data Submitters List' for bifenthrin and zeta-cypermethrin active ingredients" and "offer[ed] to pay reasonable compensation . . . for specific and valid data for which [FMC] is identified by the EPA as an original data submitter and on which these [EPA registration] applications rely." *See id.*, Ex. 2-4. FMC did not accept Sharda's offer.

On September 22, 2023, Sharda's product was conditionally registered with the EPA in accordance with section 3(c)(7)(A) of FIFRA. ECF 1-1, Ex. F. Section 3(c)(7)(A) allows for the conditional registration of a pesticide if "the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use . . . ." 40 CFR § 152.113(b). The approved product was named "Sharda Bifen. 11.25% + Zeta-Cyper. 3.75% EC," and the alternative brand name is WINNER. ECF 1-1, Ex. F. WINNER's safety data sheet, issued on September 29, 2023, indicates that the product is "[s]table under recommended storage conditions." ECF 29-9 at 7.

WINNER's product label is nearly identical to the HERO® product label. A side-by-side comparison of the labels show that WINNER has the same active ingredients mixed at the same ratio as HERO®. ECF 29-5, 29-8. The labels include similar instructions on where and when to use the products, how much product should be applied, the type of crops and pests to which the products should be applied, and the types of application equipment that are appropriate. *Id.* By giving the same crop-specific use instructions as HERO®, the WINNER label indicates that it is effective in controlling the same pests at the same dosages as HERO®. *Id.*

FMC argues that WINNER literally infringes on at least claims 1-3 and 6 of U.S. Patent No. 9,596,857 ("the '857 Patent") and claims 1-2, 4-14 and 16 of U.S. Patent No. 9,107,416 ("the '416 Patent") (collectively, "the asserted patents"). Absent the issuance of a temporary restraining order, FMC argues that it will suffer irreparable harm in the form of price erosion and loss of customers.

II. LEGAL STANDARD

To succeed in seeking a preliminary injunction, a plaintiff must establish: (1) a likelihood of success on the merits; (2) it will suffer irreparable harm without a preliminary injunction; (3) the balance of equities weighs in favor of issuing a preliminary injunction; and (4) an injunction is in the public interest. *Winter v. National Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Third Circuit has described the first two requirements as "gateway factors." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017). If the gateway factors are met, then a court should consider the remaining factors. *Id.*; *see also Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("[A] movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.,* likelihood of success on the merits and irreparable harm").

III. DISCUSSION

A. Likelihood of Success on the Merits

Demonstrating a likelihood of success in a patent infringement case requires a plaintiff to "show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). "If [the defendant] raises a substantial question concerning either infringement or validity, *i.e.,* asserts an infringement or invalidity defense that the patentee cannot prove 'lacks

substantial merit,' the preliminary injunction should not issue." *Amazon.com, Inc.*, 239 F.3d at 1350-51.

1. Infringement

"For literal infringement, the patentee must prove that the accused product meets all the limitations of the asserted claims; if even one limitation is not met, there is no literal infringement." *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1073 (Fed. Cir. 2019). The Court denied FMC's initial motion for a preliminary injunction or temporary restraining order because FMC failed to demonstrate a likelihood of success in proving infringement. Specifically, FMC did not sufficiently "establish WINNER's stability or efficacy," and "[w]ithout such evidence, this Court [was] unable to hold that WINNER meets all of the limitations of the asserted claims." ECF 25 at 10.

In its renewed motion, FMC set forth several indications of WINNER's stability, none of which Sharda disputes. In support of its EPA registration application, Sharda provided studies, including one regarding the "***Accelerated Storage Stability*** of Zeta-Cypermethrin 3.75% w/w + Bifenthrin 11.25% w/w EC." ECF 30-4 ¶ 28 (emphasis added). WINNER's safety data sheet also indicates that it is "[s]table under recommended storage conditions." ECF 29-9 at 7. This evidence, in addition to WINNER's EPA registration and the lack of acute toxicology data, speaks to WINNER's stability. Further, this Court has already found that HERO® is a stable composition. WINNER has the same active ingredients at the same ratio as HERO®, uses substantially identical instructions as HERO®, and Sharda sent "offer-to-pay" letters to FMC seeking its data. These undisputed facts establish that WINNER is likely a stable composition.

Sharda has never disputed that WINNER infringes on the asserted patents. Taking the '857 Patent as an example, claim 1, the only independent claim, consists of the following elements:

1. An insecticidal composition comprising
2. bifenthrin and
3. a cyano-pyrethroid selected from the group consisting of acrinathrin, cycloprothrin, deltamethrin, tralomethrin, fenvalerate, cyfluthrin, beta-cyfluthrin, flucythrinate, alpha-cypermethrin, beta-cypermethrin, theta-cypermethrin, zeta-cypermethrin, cyphenothrin, cyhalothrin, lambda-cyhalothrin, esfenvalerate, fluvalinate and fenpropathrin
4. wherein the composition has a ratio of bifenthrin:cyano-pyrethroid of from about 10:1 to about 1:100.

ECF 29-12 at 2. Additionally, in its July 10, 2024 opinion, the Court determined that "the claim term 'composition' must be construed to mean stable compositions[.]" ECF 25 at 8.

WINNER is a pesticide used to control insects and mites and contains a composition of 11.25% bifenthrin + 3.75% zeta-cypermethrin at a 3:1 ratio. ECF 29-8. As discussed above, WINNER is also stable. A comparison of the asserted claims to WINNER shows that WINNER meets all the limitations of the asserted claims. As a result, FMC has established a likelihood of success in proving infringement.

2. Validity

Sharda mounts its opposition on arguments that the asserted patents are invalid. More specifically, Sharda (1) reiterates its argument that the McKenzie article anticipates the asserted claims; (2) argues that the asserted patents are invalid as obvious; and (3) argues that the asserted patents are invalid under 35 U.S.C. § 112.

a. Anticipation

"A patent claim is invalid as anticipated only if each and every element of the claim is expressly or inherently disclosed in a single prior art." *Guangdong Alison Hi-Tech Co. v. Int'l Comm'n*, 936 F.3d 1353, 1363 (Fed. Cir. 2019). "[T]he dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from the prior art reference's teaching that every claim element was disclosed in that single reference." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). This Court has already found that

the intrinsic record "recognized the instability and ineffectiveness of tank mixtures like the one described in the McKenzie article . . . ." ECF 25 at 7.

Indeed, in opposition to the first motion for a temporary restraining order, Sharda relied on Table 8 in the McKenzie article. Now it relies on Table 9, but the difference is one without impact here. Dr. Neil Young's rebuttal declaration is instructive. *See generally* ECF 36-1. For example, McKenzie described multiple formulations that do *not* contain both Mustang and Capture as "consistently provid[ing] the highest level of control for all whitefly life stages." ECF 11-3 at 4. McKenzie also fails to describe which Capture, Mustang, or Orthene products were used in the purportedly effective Orthene + Mustang + Capture treatment.[2] Ironically, Sharda's counsel distinguished McKenzie from the '145 Patent's prior art disclosure on the grounds that McKenzie and the '145 Patent's prior art disclosure referenced different Mustang products and are therefore inapt comparators. Even further, Sharda cherrypicked efficacy data regarding whitefly nymphs, ignoring the less favorable data regarding whitefly eggs and whitefly adults.

In light of the foregoing, it cannot be said that "one skilled in the art would reasonably understand or infer" that McKenzie disclosed every asserted claim element. *See Dayco Prods., Inc.,* 329 F.3d at 1368. The Court concludes that McKenzie does not anticipate the asserted claims.

b. Obviousness

Next, Sharda argues that the claims of the '416 Patent are obvious in light of the prior art because "[i]t would have been obvious to a person of skill in the art to increase the amount of Capture in McKenzie's disclosed compositions to the range disclosed in the Capture label for the purpose of treating mites." ECF 35 at 18. Sharda also argues that the asserted claims are invalid as obvious because the prosecution history of U.S. Application No. 15/436,984 ("the '984

[2] Notably, McKenzie specifies which Capture or Mustang treatment is used in other tables.

application") shows that the patent examiner initially issued a final rejection of the claims because "bifenthrin to cyano-pyrethroid were known in the art to be useful in combination for pest control." *Id.* at 18-19; ECF 11-13 at 20. These arguments fail for similar reasons as the anticipation argument.

A claim is invalid as obvious if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. Sharda fails to acknowledge that the patented compositions overcame obviousness arguments due to their unexpected superior performance, resulting in the patent examiner ultimately allowing the asserted patents. *See* ECF 17-8 (explaining the '416 Patent's formulation "provide[s] unexpectedly desirable control of several insect and mite species when employed in the claimed ratios); ECF 17-10 (same with regard to the '857 Patent). As already discussed, the formulations referenced in McKenzie do not provide similarly superior results. This reality, coupled with the commercial success of HERO® and the well-known difficulty in achieving a stable formulation of bifenthrin and zeta-cypermethrin, establish that the asserted patents are not obvious to a person skilled in the art. *See* ECF 29 at ¶ 16; ECF 17-6 ("[A] problem in the art of formulating bifenthrin and zeta-cypermethrin is in successfully achieving physical stability of a water-diluted mixture of the formulation over significant periods of time. Physical stability is most important in this type of formulation to ensure the small amounts of the insecticides are fully effective").

c. Section 112

Finally, Sharda argues that the asserted claims are invalid for lack of a written description and indefiniteness under 35 U.S.C. § 112. "To fulfill the written description requirement, a patent

owner 'must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent.'" *Idenix Pharma. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019) (quoting *Carnegie Mellon Univ. v. Hoffman-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). "That test 'requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" *Id.* (quoting *Ariad Pharma., Inc v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)). Moreover, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

Sharda argues there is a lack of written description because the stability of the patented compositions is not disclosed in the specifications. It also argues that the asserted patents are indefinite because neither the claims nor the intrinsic record inform with reasonable certainty the scope of the invention. These arguments, however, fly in the face of the Court's claim construction set forth in the July 10 opinion. As noted then, the specifications of the asserted patents describe the "unexpected insecticidal activity" achieved by the patented compositions. *See* ECF 1-1 at 7, 1:48-50 ('857 Patent); ECF 1-1 at 16, 1:14 ('416 Patent). "The physical stability of the [tankmix] formulation when diluted with water is a key problem in the art." *See* ECF 17-5 at 3; ECF 25 at 8. The asserted patents addressed this key problem, as indicated by their superior results, which contributed to the allowance of the asserted patents. *See* ECF 17-8 (explaining the '416 Patent's formulation "provide[s] unexpectedly desirable control of several insect and mite species when employed in the claimed ratios); ECF 17-10 (same with regard to the '857 Patent). Accordingly, Sharda's Section 112 arguments fail as well.

At bottom, any question concerning the validity of the asserted patents lacks substantial merit. FMC has therefore demonstrated a likelihood of success on the merits.

B. Irreparable Harm

Plaintiffs seeking a preliminary injunction or temporary restraining order must make a clear showing "that irreparable injury is likely in the absence of an injunction." *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). FMC has satisfied this burden.

Price erosion, loss of market share, loss of customers, and loss of goodwill may constitute irreparable harm. *Abbott Lab'ys v. Sandoz, Inc.,* 544 F.3d 1341, 1362 (Fed. Cir. 2008). WINNER and HERO® are highly seasonal products that are primarily sold during the summer months, constituting "75% of grower purchases of [the] HERO® insecticide." ECF 4-1 at ¶ 12. Sharda admits that it has imported at least 148 cartons of WINNER into the United States, and WINNER has been sold and offered for sale in the United States. ECF 27 at ¶¶ 24-25, Prior to Sharda's importation of WINNER, HERO® was the only premixed 3:1 bifenthrin to zeta-cypermethrin insecticide on the market, consistent with its exclusivity rights. *See id.* at ¶ 7. Now Sharda and FMC are direct competitors in the market for a 3:1 bifenthrin to zeta-cypermethrin premixed insecticide product. "Because any growth experienced by [Sharda] would therefore result in lost sales to [FMC]," FMC would experience irreparable harm in the form of loss of sales and customers absent a temporary restraining order. *Natera, Inc. v. Neogenomics Lab'ys, Inc*., 106 F.4th 1369, 1378-79 (Fed. Cir. 2024); *Trebro Mfg., Inc. v. Firefly Equip., LLC,* 748 F.3d 1159, 1170 (Fed. Cir. 2014) (explaining that, in a three-player market, "every sale to [the infringer] is essentially a lost sale to [the patentee]"). In fact, the record establishes that Sharda has historically priced its generic products lower than FMC's products. *See* ECF 4-1 ¶ 10.

"[F]ailing to garner customers during the relevant season results in the loss of repeat, future customers, meaning that the loss of business opportunities is threatened as is the permanent loss of customers to a competitor." *Shibumi Shade, Inc. v. Beach Shade LLC,* No. 5:21-CV-256, 2020 WL 390839, at *16 (E.D.N.C. Feb. 8, 2022), *appeal dismissed*, No. 2023-1051, 2022 WL 17661183 (Fed. Cir. Dec. 14, 2022). This Court joins the others that have concluded "it is impossible to quantify the damages caused by the loss of a potentially lifelong customer." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). "Where the injury cannot be quantified, no amount of money damages is calculable, and therefore the harm cannot be adequately compensated and is irreparable." *Id.*; *see also Trebro Mfg., Inc.*, 748 F.3d at 1170 (acknowledging that loss of customers is an irreparable harm and money damages may be an inadequate remedy).

C. Balance of the Equities and Public Interest

For a temporary restraining order to issue, FMC must establish that the balance of hardships weighs in its favor and that granting a temporary restraining order would not disservice the public. *Apple Inc. v. Samsung Elecs. Co., Ltd.,* 809 F.3d 633, 645 (Fed. Cir. 2015). It is only rational that "requiring a patentee to compete against its own patented invention . . . places a substantial hardship on the patentee[.]" *Id.* This Court has already set forth the harms FMC will suffer if forced to compete against its own patented invention – harms that are only exacerbated given how small the market is. Any harm Sharda faces is "the result of its own calculated risk to launch" an alleged infringing product. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Indeed, "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurging Int'l Inc. v. AMF, Inc.,* 782 F.2d 995, 1003, n.12 (Fed. Cir. 1986).

The same is true with respect to the public interest prong. Courts "have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the 'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.'" *Sanofi-Synthelabo*, 470 F.3d at 1383 (quoting *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985)). Notably, Sharda has not raised any independent arguments to suggest granting a temporary restraining order would not be in the public interest.

Based on the foregoing, the Court concludes that the balance of equities weighs in favor of granting a temporary restraining order and doing so would be in the public interest.

IV. CONCLUSION

For the second time, the Court has carefully reviewed all the arguments presented in support and against the issuance of the temporary restraining order. Finding that FMC has established a likelihood of success on the merits, demonstrated a clear showing of irreparable harm, and established that the equitable factors weigh in its favor, the Court now grants the renewed motion for a temporary restraining order. Because the present record supports the issuance of a temporary restraining order, the Court denies FMC's request for expedited discovery.

An appropriate order follows.